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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,803	09/14/2001	Paul M. Meadows	AB-122U	9492

7590

12/17/2003

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,803

Applicant(s)

MEADOWS ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, “connected to at least one electrode array” is inferentially included and vague. The claim has not positively recited the electrode array for the generator to be connected to it. It is unclear if applicant is claiming the electrode array. It is suggested to first positively recite the array. In line 4, “electrical stimuli” is inferentially included and the pulse generator has not set forth that it provides electrical stimuli; “may be” is vague since it is unclear if the claim has this limitation (if it “may be” applied, this also means that it “may not be” applied, and the examiner does not need to find this limitation); and “applied to body tissue” is vague since it sounds as if there is a positive connection to the human body. Apparatus claims cannot claim a positive connection to the body. It is suggested to use something similar to “adapted to be applied”. In line 8, “at least one electrode array” is vague since it is unclear if this is the same array used in line 2. It is suggested to use “said at least...”. In line 12, “stimulation pulses” is inferentially included and it is unclear if this is the same as the electrical stimuli used in line 4. In line 13, “plurality of channels” is inferentially included. In line 14, “a program” is inferentially included. In line 16, “may be” is vague. In line 17, “an RF link” is inferentially included and it is unclear

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what element is providing this link (the programmer, the pulse generator, or both). In line 19, “may be” is vague.

In claim 2, “an RF link” is inferentially included and it is unclear if this is the same link used in claim 1. In addition, it is unclear what element is providing the link.

In claims 3 and 6, “an infra-red link” is inferentially included and it is unclear what element is providing the link.

In claim 4, “at least two electrode arrays” is vague and it is unclear if this is related to the at least one electrode array used in claim 1 or two new electrode arrays in addition to claim 1. It is suggested to use “wherein said at least one electrode array comprises at least two electrode arrays.

In claim 7, “a header connector” is inferentially included and it is unclear which element contains the header connector.

In claim 8, “an output circuit” is inferentially included.

In claim 9, “a plurality of electrode arrays”, “electrical stimuli”, “stimulation pulses” and “a stimulation program” are inferentially included. In addition, it is unclear if the stimuli are the same as the pulses. Also, “may be” and “applied to body tissue” are vague.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 5, and 9 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fischell et al (EP 0911061).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischell et al. Fischell provides a connector, 8, for the electrodes which is the header connector.

In the alternative, Fischell discloses the claimed invention except for the header connector on the implantable device to detachably connect the electrode array. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pulse generator as taught by Fischell, with a header connector to detachably connect the electrode array since it was known in the art that implantable pulse generators use header connectors to detachably connect the electrode array to the pulse generator to allow the electrode array(s) to be easily implanted or explanted by itself and then connected/uncoupled to the pulse generator to prevent a tangling of wires between themselves and with the pulse generator.

Claims 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.

Fischell discloses the claimed invention except for the diagnostic system or clinician programmer coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator (claims 3 and 6) and capacitively coupling the array to the pulse generator (claim 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the external and implantable system as taught by Fischell, with a diagnostic system or clinician programmer

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coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator and capacitively coupling the array to the pulse generator since it was known in the art that external and implantable systems use the diagnostic system or clinician programmer coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator to allow the diagnostic system to quickly, inexpensively, and easily reprogram the HHP or pulse generator without the use of wires that may become tangled and time to connect the wires and since it was known in the art that external and implantable systems use capacitively coupling of the array to the pulse generator to reduce unwanted noise and signals in the array and pulse generator and/or to provide a balanced charge to the electrodes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

GRE
December 11, 2003


GEORGE R. EVANISKO
PRIMARY EXAMINER

12/11/03